



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

RW

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/461,774	12/15/99	CHAN	L 1781-180P

HM22/1002  
BIRCH STEWART KOLASCH & BIRCH LLP  
PO BOX 747  
FALLS CHURCH VA 22040-0747

EXAMINER	
SWARTZ, R	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED:  
10/02/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**BEST AVAILABLE COPY**

<b>Office Action Summary</b>	Application No. <b>09/461,774</b>	Applicant(s) <b>Chan et al</b>
	Examiner <b>Rodney P. Swartz, Ph.D.</b>	Group Art Unit <b>1645</b>

Responsive to communication(s) filed on 19May2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-26 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 1-26 are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit:

## DETAILED ACTION

### Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-9, drawn to polypeptides, classified in class 424, subclass 248.1.
  - II. Claims 10-13, 22, 23, drawn to method of isolating polypeptides, classified in class 436, subclass 501.
  - III. Claims 14-17, drawn to DNA, classified in class 536, subclass 23.7.
  - IV. Claims 18-19, drawn to antibody, classified in class 424, subclass 168.1.
  - V. Claim 20, drawn to method of detection using antibody, classified in class 435, subclass 7.32.
  - VI. Claim 21, drawn to apparatus, classified in class 435, subclass 4.
  - VII. Claims 24-26, drawn to method of treatment, classified in class 424, subclass 9.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III, IV, V, VI are drawn to structurally and functionally distinct inventions. Invention I is drawn to polypeptides, Invention III to DNA, Inventions IV and V to antibody, Invention VI to an apparatus.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the

Art Unit:

polypeptides can be made using isolated DNA in transformed hosts of another genus of microorganisms.

Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Invention I can be used in immunoassays for detection of infection by *Mycobacteria*.

Invention II and III-VI are drawn to structurally and functionally distinct inventions. Invention II is drawn to polypeptides, Invention III to DNA, Inventions IV and V to antibody, Invention VI to an apparatus.

Invention II and Invention VII are two distinct methods using different reagents with different end results.

Invention III and IV-VII are drawn to structurally and functionally distinct inventions. Invention III to is drawn to DNA, Inventions IV and V to antibody, Invention VI to an apparatus, Invention VII to polypeptides.

Invention IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

Art Unit:

§ 806.05(h)). In the instant case, the antibody of Invention IV can be used to passively immunize subjects against infection with *Mycobacteria*.

Inventions IV and VI-VII are drawn to structurally and functionally distinct inventions. Invention IV is drawn to antibody, Invention VI to an apparatus, Invention VII to polypeptides.

Invention V and VI-VII are drawn to structurally and functionally distinct inventions. Invention V is drawn to antibody, Invention VI to an apparatus, Invention VII to polypeptides.

Invention VI and VII are not related. Invention VI is drawn to an apparatus for *in vitro* assays, Invention VII to a method of *in vivo* treatment.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and because while the searches may overlap, the searches are not coextensive, restriction for examination purposes as indicated is proper.

#### **Election of Species**

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

**First Election of Species:** chose one of the species in claim 2

**Second Election of Species:** chose one of the molecular weights in claims 6-7

**Third Election of Species:** chose one of the amino acid sequences in claims 8-9

Art Unit:

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 10, 13, and 14 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CAR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CAR 1.143).

Art Unit:

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CAR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CAR 1.48(b) and by the fee required under 37 CAR 1.17(I).

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

  
RODNEY P. SWARTZ, PH.D  
PRIMARY EXAMINER

Art Unit 1645

September 29, 2000